Exhibit A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No.1456 Master File No. 01-CV-12257-PBS Subcategory No. 06-CV-11337-PBS
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al.*, Civil Action No. 07-10248-PBS	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

THE ROXANE DEFENDANTS' MEMORANDUM
IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The Government's lawsuit against Roxane, a small manufacturer of generic drugs, suffers from numerous fatal defects. Until now, the law has afforded the Government certain pleading privileges that kept the case viable. But the credit of allegations does not last forever. Instead, summary judgment places these allegations at a critical juncture, as the Government is now required to produce sufficient competent evidence to establish a triable issue of fact on each of the elements of its causes of action. This Motion demonstrates the fundamental shortcomings in the Government's case – evidentiary voids that entitle Roxane to summary judgment on each and every issue discussed below. And, by addressing these shortcomings now, this Court will significantly pare down the issues to be tried by a jury.

First, because the Government has come forward with *no* evidence that each Medicaid claim was actually paid using Roxane's AWPs or WACs, the Government cannot meet the required elements of a "false claim" or materiality for its False Claims Act counts. Moreover, all Medicaid claims for which the Government relies on incompetent data should be excluded because the Government cannot establish the elements of falsity or causation. Likewise, summary judgment should be entered on all claims that were not paid based on Roxane's AWPs or WACs, or were not paid pursuant to a CMS-approved reimbursement formula, because the Government has failed to establish a causal link between Roxane's conduct and the actual payment on those claims.

Second, the Government cannot seek Medicare damages that are based on the misclassification of the Novaplus-label ipratropium bromide as a brand. Thus, all damages that depend on errors by the Medicare Carriers in classifying drugs or timely updating prices should be dismissed because the Government cannot establish that those "damages" were a direct and proximate result of Roxane's conduct. Furthermore, all damages that depend on carrier

misclassification should be excluded because the Government cannot establish scienter for the claims involved. Excluding claims based on the Carriers' errors and omissions reduces damages by nearly $1 billion.

Third, summary judgment should be entered in favor of defendants on all Medicaid and Medicare claims post-December 31, 2000 because the Government cannot prove the elements of scienter or falsity for claims submitted after that date. As this Court has held, by 2001, at the latest, the "perfect storm of information" revealed the nature of AWPs and the extent of significant discounts available in the marketplace to purchasers of generic drugs. The record evidence in this case further bolsters this Court's finding and demonstrates that an abundance of information about the pricing of generic drugs, much of which is specific to the very drugs at issue here, was available to the Government.

Fourth, all pre-2001 claims should be excluded because they are time-barred due to the Court's lack of jurisdiction over Ven-A-Care's underlying claims.

Finally, the Government's unjust enrichment claims should be dismissed because there is no evidence that Roxane was unjustly enriched. Likewise, all damages for Medicare claims relating to azathioprine should be dismissed because the Government has no evidence to support that element.

LEGAL STANDARD

Summary judgment is appropriate where, as here, "'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.'" *Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36-37 (1st Cir. 1995) (quoting Fed. R. Civ. P. 56(c)); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). An issue is "genuine" for purposes of summary judgment only if '"the evidence is such that a

reasonable jury could return a verdict for the nonmoving party,'" and a "material fact" is one which '"might affect the outcome of the suit under the governing law.'" *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Summary judgment "may be sought and entered on any part of a case." *Gore v. Trs. of Deerfield Acad.*, 385 F. Supp. 2d 65, 68 (D. Mass. 2005) (citing Fed. R. Civ. P. 56(b)).

I. THE GOVERNMENT CANNOT PREVAIL ON ANY MEDICAID CLAIM WHICH IT CANNOT PROVE WAS PAID BASED ON ROXANE'S AWPS OR WACS.

A. The FCA Requires Proof Of A "False Claim" And Materiality.

Under the False Claims Act ("FCA"), the Government must come forward with sufficient evidence of an actual false claim to avoid summary judgment. Indeed, evidence of an actual false claim is "the *sine qua non* of a FCA violation." *U.S. ex rel. Clausen v. Laboratory Corp. of America, Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002). As the First Circuit holds, "[n]ot all fraudulent conduct gives rise to liability under the FCA. 'The statute attaches liability, not to the underlying fraudulent activity or to the Government's wrongful payment, but to the claim for payment.'" *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004). Thus, to survive a motion for summary judgment, the Government must present evidence that each of the Medicaid claims at issue in this lawsuit was in fact false. *See U.S. ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432 (3rd Cir. 2004).

Once the Government has established a "false" claim, it must then have sufficient evidence to show that the false claim was material. *Massachusetts v. Mylan Labs., et al.*, 608 F. Supp. 2d 127, 152 (D. Mass. 2008). A false statement is material if it "has a natural tendency to influence agency action, or is capable of influencing, agency action." *Id.* at 153 (internal citations omitted). It follows that there can be no showing of materiality where the underlying predicate – a false claim – has not been established. *Id.* The upshot here is that to

survive summary judgment the Government must show that Roxane's AWPs and WACs were actually "used to compute EAC [estimated acquisition cost] . . . ." *Id.*

B. Because The Government Has No Evidence To Prove That Claims Were Actually Paid Based On False AWPs Or WACs, Its Medicaid Counts Cannot Survive Summary Judgment.

The Government must come forward with evidence that each State Medicaid program actually paid each claim for which it seeks recovery using Roxane's AWPs or WACs. The Government cannot meet this burden because it never sought to determine this. (*See* 56.1 ¶ 275) Instead, as discussed below, the Government simply calculates the difference between the paid amount on a Medicaid claim and what the Government contends "would" have been paid, had the State's payment been based on a hypothetical "true" AWP or WAC. (56.1 ¶¶ 258, 285) This calculation improperly *assumes* – and does not establish with evidence – that the payments for all Medicaid claims were actually based on Roxane's AWPs and WACs. *See Mylan*, 608 F. Supp. 2d at 153.

But liability cannot attach on the mere assumption that an alleged "false claim" has been presented to the Government. Rule 56 demands "sufficient evidence." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Here, the factual record reveals an "absence of evidence to support the [Government's] position." *Mylan*, 608 F. Supp. 2d at 139 (quoting *Rogers v. Fair*, 902 F.2d 140, 143 (1st Cir. 1990)). This lack of evidence dooms not only the "false claim" element of the Government's FCA counts, but also materiality, which cannot be shown without evidence of an actual false claim. *Id.* at 152.

II. ROXANE IS ENTITLED TO SUMMARY JUDGMENT BECAUSE THE GOVERNMENT CANNOT ESTABLISH LIABILITY OR DAMAGES THAT ARE NOT BASED ON STATE MEDICAID CLAIMS DATA.

The Court previously held that to have a viable claim a plaintiff must show that the Medicaid claims at issue were paid on the basis of the allegedly false AWPs or WACs.

In re Pharm. Industry Avg. Wholesale Price Litig., 478 F. Supp. 2d 164, 180-81 (D. Mass. 2007). Here, the Government fails to use State Medicaid claims data to establish either liability or damages. As discussed below, that failure forecloses its ability to prove causation or other requisite elements of its claims.

A. Roxane Is Entitled To Summary Judgment On Claims Relating To Thirty-Three Medicaid Programs Because The Government Improperly Relies On An Extrapolation To Establish Both Liability And Damages.

Despite the fact that the Government had State Medicaid claims data for thirty-one States, it did a state-specific analysis of Medicaid claims data associated with only sixteen State Medicaid programs. (56.1 ¶¶ 261-62) The Government completely failed to obtain State Medicaid claims data from the other eighteen State Medicaid programs. (56.1 ¶ 262) Thus, for thirty-three of the forty-nine Medicaid programs the Government does not attempt to prove liability or damages with actual data from that State. Instead, in those States, the Government performs a faulty extrapolation from its sixteen-state sample "damages" calculation. The Government's analysis is fatally flawed in several respects.

First, in attempting to extrapolate from sixteen States to thirty-three States, the Government completely ignores the fundamental predicate to FCA liability in its sample: the percentage of claims actually paid using Roxane's AWPs or WACs.[1] For most of the State Medicaid programs at issue, the Government relies on CMS datasets from which it is not possible to determine the payment basis. (56.1 ¶¶ 267-68) Moreover, even when the Government utilizes State Medicaid claims data, it willfully ignores the baseline inquiry of how

[1] As discussed *infra*, the Government calculates damages on claims paid in Massachusetts based on AWP, notwithstanding this Court's dismissal of all AWP-based claims as a matter of law in the Massachusetts case. Not only is it inappropriate to calculate damages on such AWP-based reimbursements, but also the Government compounds the problem by extrapolating those Massachusetts claims to the thirty-three other Medicaid programs. (56.1 ¶ 273)

a particular claim was paid. (56.1 ¶¶ 269, 275) Indeed, while theoretically the Government bases its extrapolation on the data it actually has from sixteen States, those sixteen States lacked claims data for numerous quarters. (56.1 ¶¶ 287-90) In a number of instances, the Government bases its extrapolation on significantly less than the Medicaid claims data of sixteen States. For instance, in 2007Q4 for NDC 0054-4297-31, only two States within the sixteen-state sample have State Medicaid claims data. (56.1 ¶¶ 289, 292) Therefore, for this NDC and in this quarter, the Government utilizes State Medicaid claims data from just two States to extrapolate to thirty-three other State Medicaid programs.[2] (56.1 ¶¶ 289, 291) Although this Court has repeatedly found that the FCA requires a claim-by-claim analysis, *see, e.g., In re Pharm. Industry Avg. Wholesale Price Litig.*, 478 F. Supp. 2d at 164, 181; *Mylan*, 608 F. Supp. 2d at 147-48, the Government has no claim-specific information to support its allegations here other than the amount paid. There is thus no evidence of why or how the State paid the particular amount for any claim, much less that the payment was connected to Roxane's AWPs or WACs.

In the absence of this actual evidence, the Government simply points to the amount paid by a State Medicaid program and shows that it is greater than the imagined "true" AWP that the Government's expert has calculated. (56.1 ¶ 258) This naked comparison, the Government argues, satisfies its burden of establishing liability and damages when used as a basis to extrapolate to thirty-three other Medicaid programs – regardless of whether or not the Government has in its possession actual Medicaid claims data for those States. (56.1 ¶¶ 291-93) But simply showing a difference between an imagined AWP and a paid amount essentially puts the cart before the horse when there is no initial showing of liability. Liability must be the

[2] To show liability and damages for the other fourteen Medicaid programs within its sixteen-state sample, the Government performs an intrastate extrapolation to CMS datasets. (56.1 ¶¶ 287-90)

predicate inquiry and that requires the Government to show that the amount paid on a Medicaid claim was premised in some way on Roxane's AWPs or WACs. The Government's "evidence" for thirty-three Medicaid programs – which does not include State Medicaid claims data and thus can prove no such connection – falls woefully short of that mark.

Second, as discussed in Section III below, the Government fails to consider the payment basis on any Medicaid claim.[3] Without examining the basis of payment on any claim, the Government improperly assumes liability and damages when it extrapolates to CMS datasets. Neither liability nor damages can be assumed, however, especially in a Medicaid case involving forty-nine different Medicaid programs, with different payment practices, different levels of knowledge, and different policy choices embedded into each drug claim payment. (56.1 ¶ 272, at Tab 199, pp. ii-iii) In fact, as the OIG observed in its review of State Medicaid payments, even States with the same Estimated Acquisition Cost ("EAC") formula at times pay substantially different prices for the same drugs. (56.1 ¶ 272, at Tab 199, pp. iii, 17) As a result, even knowing the reason one State paid a particular amount on a Medicaid claim does little to explain the reasons why another paid a substantially different amount for the same drug, even if the EAC formula is the same.

No case law under the FCA permits a plaintiff to circumvent its burden of proof of liability in this fashion.[4] And while the First Circuit has recognized statistical extrapolation as a

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[3] The actual billed amount – typically referred to as the usual and customary charge – submitted by the provider typically appears in the State Medicaid claims data. (56.1 ¶¶ 263, 276) The Government considers the payment basis on claims only in the sense that it discards those claims in which the billed amount is lower than the paid amount, as well as claims in New York that were subject to federal upper limits ("FUL"). (56.1 ¶¶ 275, 283-84)

[4] Although this Court has stated, "extrapolation is a reasonable method for determining the number of false claims," *U.S. ex rel. Loughren v. UnumProvident Corp.*, 604 F. Supp. 2d 259, 261 (D. Mass. 2009), that decision does not support the manner in which the Government has sought to estimate damages on CMS datasets. First, in *Loughren*, this Court excluded plaintiff's proposed expert statistician because his (Continued…)

valid method of estimating overpayments in Government recoupment actions, *United States v. Lahey Clinic Hospital, Inc.*, 399 F.3d 1, 18, n.19 (1st Cir. 2005), it has not done so in a case alleging fraud under the FCA.[5] Recoupment actions typically involve a random sample of claims, which the Government audits for regulatory compliance. *Ratansen v. Cal. Dep't of Health Servs.*, 11 F.3d 1467, 1470 (9th Cir. 1993). In that context, it is the healthcare provider's burden, not the Government's, to prove entitlement to the payment received, as the Government need only show payment over and above the amount authorized by the regulations. *Id.* In FCA cases, however, the Government must prove all elements (including scienter, falsity, and causation) of its claims and sampling procedures have been recognized as an ill-suited vehicle by which to detect, let alone prove, fraud.[6]

Accordingly, Roxane is entitled to summary judgment on all the Medicaid claims for the thirty-three Medicaid programs in which the Government relies on an extrapolation to establish liability, which would serve to reduce substantially the Government's Medicaid case. (56.1 ¶ 295)

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methodology was insufficiently reliable. Second, the plaintiff's expert in *Loughren* sought to determine, with a statistical sampling of claims, the percentage of claims that were false. In contrast, the Government here assumes all claims submitted to the Medicaid program for the NDCs at issue were false and seeks to use statistical sampling to determine the amount of alleged damages. For the reasons described above, an extrapolation from Medicaid claims data to CMS datasets cannot establish damages, let alone liability.

5 In *Lahey*, the United States brought a suit seeking restitution and prejudgment interest for alleged Medicare overpayments, not fraud. 399 F.3d at 3, 6 (appeal concerning subject matter jurisdiction). In response to the hospital's argument that the case was too complex to be tried in federal court, the First Circuit stated in *dicta* that a "sampling of similar claims and extrapolation from the sample is a recognized method of proof." *Id.* at 18, n.19 (citing *Chaves County Home Health Serv., Inc. v. Sullivan*, 931 F. 2d 914, 919 (D.C. Cir. 1991) (challenge to agency recoupment for Medicare overpayments); and *Ratansen v. Cal. Dep't of Health Servs.*, 11 F.3d 1467, 1471 (9th Cir. 1993) (use of extrapolation to determine overpayments was appropriate)).

6 "Estimating a fraud rate is almost impossible to calculate because fraud reflects a legal definition involves establishing intent and weighing the merits of a case against standards." (56.1 ¶ 291, at Tab 218, Daniel R. Levinson, the HHS Inspector General, Questions by Chairman Tom Coburn for Daniel Levinson)

B. Roxane Is Entitled To Summary Judgment Where Claims Data Was Not Used In The Calculation Of Alleged Medicaid Damages Relating To Sixteen Medicaid Programs.

As noted above, the Government attempts to establish liability and determine specific actual, data-based damages for only sixteen States. In a number of instances, however, even with its sixteen-state sample set, the Government does not rely on or use actual State Medicaid claims data as part of its damages calculation. (56.1 ¶¶ 288-89) For the same reasons as discussed above, Roxane is entitled to summary judgment on those claims where the Government fails to use State Medicaid claims data. (*See* 56.1 ¶ 294)

III. ROXANE IS ENTITLED TO SUMMARY JUDGMENT ON ANY CLAIM NOT PAID ON THE BASIS OF A PUBLISHED EAC FORMULA THAT IS DEPENDENT ON AWPS OR WACS.

A. Summary Judgment Is Warranted On All Medicaid Claims Not Paid Pursuant To Published And CMS-Approved State Reimbursement Formula.

The Government fails to consider whether any claim was paid consistent with the governing regulatory framework.[7] *See Mylan*, 608 F. Supp. 2d at 147. As the Government's expert concedes:

> Q. Did you go through – for every claim where you calculated a difference did you verify that the state was following a CMS approved formula in adjudicating the claim?
>
> * * *
>
> A. I did not examine whether each state's adjudication method at a point in time – I did not examine whether the adjudication methods were approved by CMS. (56.1 ¶ 269)

Establishing the basis of a State Medicaid program's payment of a particular amount for a specific claim is a critical undertaking because there must be a "causal link between the

[7] *See supra* n.3.

defendant['s] actions" and the actual payment. *In re Pharm. Industry Avg. Wholesale Price Litig.*, 478 F. Supp. 2d at 181. In fact, this Court has previously held that even if a State paid a Medicaid claim based on a defendant's published prices that may not be enough to satisfy the liability elements of the FCA, if that payment was not consistent with the State's regulation. *Mylan*, 608 F. Supp. 2d at 147-48. Tellingly, the Government's own expert recognizes that claims reimbursed on a basis other than an approved-regulatory formula should be "drop[ped]" from any damages calculation. (56.1 ¶ 284) For example, the Government's expert discards any claim where the amount paid by the State Medicaid program is greater than the amount billed by the healthcare provider (the usual and customary charge ("U&C")).[8] (*Id.*) But paying more than a billed amount is just one of many circumstances where State Medicaid programs depart from their regulatory formulae when paying Medicaid claims. *See, e.g.*, *Mylan*, 608 F. Supp. 2d at 134, 147-48 (56.1 ¶¶ 283-84, 269-74)[9].

Indeed, the Court has confronted instances in which a Medicaid program has not paid drug claims according to its regulations. In Massachusetts, the Court observed the undisputed fact that "[i]n certain cases, [Massachusetts] reimbursement exceeded the EAC and the FUL." *Mylan*, 608 F. Supp. 2d at 133. Moreover, in Massachusetts, this Court found that liability could *not* be established on claims reimbursed based on AWP, because that payment basis was not authorized by the State's CMS-approved Medicaid plan or regulations. *Id.* at 147-48.

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[8] In fact, when analyzing State Medicaid claims data, the Government's expert eliminates hundreds of thousands of claims from his damages analysis. In Georgia, for example, he discards over 214,000 claims, which represent 56% of the total claims he analyzed in that State, because the amount paid by the Medicaid agency exceeds the amount billed by the provider. (56.1 ¶ 284)

[9] For instance, as detailed in Roxane's 56.1 statement, several Medicaid programs departed from Medicaid regulations when paying claims. (56.1 ¶¶ 269-74) Nonetheless, the Government makes no effort to discard those claims from its liability analysis. The Government then compounds the problem when it relies upon faulty claims in States such as Florida to extrapolate to other Medicaid programs. (56.1 ¶¶ 261, 289, 291)

Accordingly, here, liability cannot attach to claims paid in a manner not authorized by regulations where there is no evidence that a manufacturer was aware of that reimbursement practice.[10]

B. The Government Cannot Establish Liability For Any Medicaid Claim That Was Paid On A Basis Other Than The EAC.

The Government is also foreclosed from recovering, at a minimum, any claims paid on the basis of a FUL, MAC, or U&C – all of which break the chain of causation between Roxane's AWPs and WACs and the harm alleged in the complaint. The Government's allegations with respect to purportedly "inflated" AWPs and WACs do not hold true when a State Medicaid program paid a claim on an alternative basis such as a state MAC, FUL, or U&C. Medicaid claims are subject to a variety of potential payment bases that do not involve Roxane's AWP or WAC. In Rhode Island, for example, whenever a WAC was not available in the drug pricing compendia, the State Medicaid program would only pay claims on the basis of the FUL or the billed amount. (56.1 ¶ 277) Roxane did not supply WACs to the compendia for its generic products, which means that Rhode Island could not have paid any Medicaid claim on any such products on the basis of Roxane's conduct. (*Id.*)

Similarly, although several of the NDCs at issue were subject to FUL payment limits, the Government admits that none of those FUL prices was set by Roxane's published prices. (56.1

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[10] The Government in this case continues to assert liability and damages on claims in Massachusetts during the years 1999-2003 that were reimbursed on the basis of AWP, despite the fact that this Court has ruled as a matter of law such claims were properly dismissed. The Government has offered no evidence in this case that Roxane "understood that [it was] being reimbursed on the basis of an EAC calculated using [its] AWPs" and therefore summary judgment should enter on those claims. *Mylan*, 608 F. Supp. 2d at 148. Moreover, as discussed *supra* Section I, the fact that the Government's damages expert utilizes these Massachusetts claims to estimate damages in other States is another reason that its extrapolation fails as a matter of law.

¶ 120, at Tab 139) Nor does CMS mechanically follow the requirements of the FUL regulation in any event. (56.1 ¶¶ 118, 121-123).

Likewise, for most of the relevant period in this lawsuit, numerous State Medicaid programs set MAC prices for generic drugs. (*Id.* ¶ 279). Many of them did not base their MAC prices on AWPs or WACs, which breaks the causal link. *In re Pharm. Industry Avg. Wholesale Price Litig.*, 478 F. Supp. 2d at 181; *see also* (56.1 ¶ 279). Moreover, the Government has produced *no* evidence that any State based its MAC prices on Roxane's AWPs or WACs, which forecloses any recovery on claims paid pursuant to any state MAC price.

Finally, the U&C is completely untethered to Roxane's published AWPs or WACs. It is a price submitted by providers on every Medicaid claim and its definition varies from State-to-State. (56.1 ¶ 276) Some States define U&C as the price paid by retail or cash-paying customers, but other States have adopted "best price" or "most favored nation" definitions, which require the pharmacy to submit the lowest price charged or accepted from any customer or reimburser. (*Id.*) In any event, any claim paid on a U&C is not linked to Roxane's AWPs or WACs and thus cannot be a false claim attributable to Roxane.

IV. CLAIMS THAT DEPEND ON THE DMERCS' MISCLASSIFICATIONS AND OTHER ERRORS SHOULD BE DISMISSED.

The Government presents two independent damages models for Roxane's drugs: one that correctly excludes damages created by the Medicare Durable Medical Equipment Regional Carriers' (the "DMERCs") misclassifications of the Novaplus-label ipratropium bromide as a brand (the "No Novaplus Model"), and the other that includes Novaplus ipratropium bromide

when it was misclassified as a brand (the "Novaplus Model").[11] (56.1 ¶¶ 225-44) The differences between the two damages models are staggering – the Government alleges a figure of $234 million for its No Novaplus Model, but then inflates its figure to $1.17 billion for the Novaplus Model. (56.1 ¶ 243) Although the misclassification of Novaplus as a brand had no impact upon Medicare payments in the real world (because the Novaplus and Roxane-label AWPs were identical at all times), the Government's recreation of a "but for" world under the Novaplus Model creates a massive hypothetical impact. (56.1 ¶¶ 237-42) Specifically, the Government replaces the actual Novaplus AWPs with "revised AWPs" based on sales transactional data. (56.1 ¶ 226) Because the regulations allowed payments to be based on "the lowest brand AWP," in the Government's "but-for" world the DMERCs' misclassification of Novaplus as a "brand" allows the Government to convert the "revised Novaplus AWP" into the new "lowest brand AWP." (56.1 ¶¶ 240-42) As a result, these "revised Novaplus AWPs" now become the hypothetical payment bases for *all* quarters and *all* ipratropium bromide claims, even though it is unlikely that *any* Novaplus products were ever reimbursed under Medicare Part B. (*Id.*)

No doubt uncomfortable with the disparity between the two models, the Government's own damages expert, Dr. Duggan, acknowledged that while including Novaplus ipratropium bromide in the model has a "massive" impact on the Government's damages, the Novaplus NDCs had *extremely* low utilization under Medicare Part B – potentially accounting for only 150

[11] The Novaplus-label ipratropium bromide was a generic product identical to the Roxane-label ipratropium. It received a Novaplus-label because it was a private label product sold exclusively to Novation GPO's hospital members. (Novation used the "Novaplus label" to identify its products.) (56.1 ¶¶ 140-50).

out of more than ***12 million*** ipratropium bromide claims under Part B.[12] (56.1 ¶¶ 151-55, 242-44) Dr. Duggan further admitted there is a "good case" for excluding Novaplus ipratropium bromide altogether from the Government's damages. (56.1 ¶ 244) Dr. Duggan is right.

The Government's claim for relief, premised on the inclusion of Novaplus ipratropium bromide, is flawed for a number of reasons. Most critically, the Novaplus Model hinges on how the DMERCs classified the Roxane and Novaplus-label ipratropium bromide products as generics or brands. Yet, the undisputed evidence shows that three of the four DMERCs, entrusted with making accurate and consistent distinctions between generic and brand drugs, disregarded the Health Care Financing Administration's ("HCFA")[13] regulatory definitions and mandates, and instead implemented an unreliable, labyrinthine set of internal procedures and criteria that had no resemblance to the regulatory definition. Moreover, the DMERCs routinely failed to adhere even to their own internal classification criteria. As a result, the DMERCs' classifications of Roxane's generic products were random and unpredictable, replete with gross errors and blatant inconsistencies.

Importantly, Roxane's reporting of allegedly "inflated" AWPs had *nothing* to do with the DMERCs' independent decision-making process for classifying drugs or updating prices. Thus, there can be no causal connection between Roxane's conduct and the theoretical loss occasioned by the DMERCs' determination of whether a drug was a generic. And there is not a shred of evidence suggesting that Roxane could foresee the inconsistent (and often indecipherable) methodology employed by the DMERCs, let alone know that they in fact misclassified the

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[12] The reason there were so few (if any) Novaplus-label ipratropium bromide claims under the provisions of Medicare Part B at issue here is that these products were sold exclusively to hospitals. (*See* 56.1 ¶¶ 151-55)

[13] HCFA was renamed the Centers for Medicare and Medicaid Services ("CMS") in 2001.

Novaplus-label ipratropium bromide as a brand.[14] To the contrary, because the DMERCs' internal procedures were not public, these errors remained entirely unknown to Roxane. Thus, there is ***no*** basis in law (or economics) to attribute to Roxane massive damages based on the vagaries of the DMERCs' error-ridden procedures.

A. The False Claims Act Limits Recovery Solely To Damages That Are Foreseeable And Closely Connected To The Alleged Conduct.

The FCA provides for automatic treble damages, and therefore its damages provisions are punitive in nature. *Vermont Agency of Natural Res. v. United States*, 529 U.S. 765, 784-85 (2000). Accordingly, courts typically apply a proximate causation standard to "narrow, rather than enlarge, the field of actions for which FCA liability may be imposed." *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield*, 472 F.3d 702, 714-15, n.17 (10th Cir. 2006). Indeed, this Court previously determined that general causation principles derived from tort law apply to the FCA. *See U.S. ex rel. Franklin v. Parke-Davis*, No. CIV. A. 96-11651 PBS, 2003 WL 22048255 at **4-6 (D. Mass. Aug. 22, 2003).[15] Accordingly, a plaintiff must have competent evidence to demonstrate that the alleged false statements were the proximate cause of the alleged damages. This requires evidence to establish that the resulting damage was foreseeable and had a sufficiently close nexus to the defendant's conduct. *Id.* at **4-5. When an unforeseeable intervening factor causes the alleged harm, that intervening factor breaks the chain of legal causation and a plaintiff cannot recover damages. *See id.* at *5 (citing *U.S. ex rel. Cantekin v.*

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[14] Nor is there any evidence that Roxane intended for the Novaplus-label ipratropium bromide to be considered anything other than a generic in the marketplace. *See infra* Section V.

[15] *See generally U.S. ex rel. Fago v. M&T Mortgage Corp.*, 518 F. Supp. 2d 108, 122 (D.D.C. 2007) (noting the majority rule applying proximate cause analysis for both liability and damages under the FCA); *Sikkenga*, 472 F.3d 702 at 714 (citing *United States v. Hibbs*, 568 F.2d 347, 349 (3rd Cir. 1977) for proposition that "traditional principles of tort law" apply to causation for damages under the FCA).

Univ. of Pittsburgh, 192 F.3d 402, 416 (3rd. Cir. 1999) and applying intervening factor analysis). Thus, causation under the FCA requires a substantially stronger evidentiary showing than a mere "but for" cause of any alleged losses. *See U.S. ex rel. Fago v. M&T Mortgage Corp.*, 518 F. Supp. 2d 108, 122 (D.D.C. 2007). As shown below, the Government cannot meet this standard.

B. The DMERCs' Disregard Of Regulatory Mandates For Distinguishing Generics From Brands Is An Intervening Factor That Negates Causation.

1. HCFA's Regulations And Directives Required DMERCs To Classify Generic Drugs Based On Whether They Were Named After The Underlying Generic Chemical Compound.

On November 2, 1998, HCFA implemented a final rule that revised its payment methodology for generics under Medicare Part B to include consideration of AWPs for brand drugs. (56.1 ¶ 174) HCFA adopted a payment formula for generic drugs that required the four DMERCs to compare "the lower of the median price of the generic AWPs" with "the lowest brand name AWP," and then pay the lower amount. (*Id.*) In response to a comment generated during the rule making process, HCFA provided the following definition of a "brand" for purposes of Medicare Part B payments:

> Our definition of "brand" is any product that is marketed under a name other than the generic chemical name of the drug. If a manufacturer chooses to market its product under a proprietary name rather than the generic chemical name of the drug, we believe this is a brand.

(56.1 ¶ 175) In December 1998, HCFA issued a Program Memorandum that directed the DMERCs to implement these November 1998 regulatory changes. (56.1 ¶¶ 176, 178) This HCFA directive specifically included the above regulatory definition. (*Id.*)

The Novaplus-label ipratropium bromide product met the regulatory criteria for a generic, not a brand, drug. It was marketed under its full generic chemical compound name of "ipratropium bromide inhalation solution 0.02%" and listed in the publishing compendia as such,

(56.1 ¶¶ 142-47), as were all other generic ipratropium products. (56.1 ¶ 139) Indeed, the Medicare Supplier Bulletin that preceded the regulatory definition specifically listed "Ipratropium bromide" as a generic name and "Atrovent" as the companion "Trade/Brand" name. (56.1 ¶ 177) Thus, the product was not marketed under a "propriety name rather than the generic chemical name of the drug," and, accordingly, should not have been classified as a brand by any DMERC. In any event, as shown directly below, the DMERCs ignored HCFA's regulatory definition, and instead privately adopted an unrelated alternate methodology.

2. The DMERCs' Idiosyncratic And Private Procedures Were Inconsistent With Regulatory Definitions and HCFA Directives.

The undisputed evidence demonstrates that the DMERCs' actual procedures– which were entirely unknown to Roxane – ignored HCFA mandates.[16] (56.1 ¶¶ 162, 174-82) Although the governing regulation *required* the DMERCs to classify drugs marketed under the "generic chemical name" (here, "ipratropium bromide") as generics, the DMERCs in fact paid no attention to that criteria. (56.1 ¶¶ 174-82) Instead, they adopted an entirely different private methodology that depended principally on whether a drug name was capitalized in the Redbook compendia, which apparently revealed only whether a drug was *generally* – not necessarily – a brand:

> To determine if a drug is generic or brand, look at the bold face upper case name of the drug [in the Drug Topics Redbook publication]. If there is another name for the drug immediately below it in lower case letters (the generic name), the entries following are <u>generally</u> brands. If there is no lower case drug name immediately below the bold face upper case name, the bold face upper case name is the generic name and all the entries below are generics. In either case, if an entry below the drug name refers to another page, that entry would be for a brand name. If there is a question as to whether a drug is brand or generic, consult the PDR Generics, telephone the drug company or **Redbook** (1-800-222-3045).

[16] For an overview of the DMERCs' construction of pricing arrays, (*see* 56.1 ¶¶ 156-73, 179).

(56.1 ¶ 180) (emphasis in original).

Although the DMERCs' disregard of regulatory criteria in itself negates causation, s*ee* *Mylan,* 608 F. Supp. 2d at 147-48, the causal chain is further attenuated here by the additional fact that the DMERCs failed to apply even their own internal procedures in a predictable – or foreseeable – manner. (56.1 ¶¶ 179-224) For instance, the DMERCs implemented their procedures in widely divergent ways, often relying on different underlying data, updating arrays at different times and in different ways, and exercising independent, and often conflicting, discretionary choices. (56.1 ¶¶ 162-73) Indeed, both HCFA and the DMERCs were well-aware of long-standing inconsistencies and problems with the DMERCs' pricing of drugs. (56.1 ¶¶ 164-73)

Not surprisingly, given the indecipherable written procedures quoted above and the varied methodology adopted in practice, the DMERCs' classifications of Roxane's generic products were chaotic: only one of the four DMERCs (DMERC-A) correctly and consistently placed the Novaplus and Roxane-label generic products consistently in its generic arrays throughout the pertinent time period. (56.1 ¶ 221) The other three DMERCs misclassified either the Novaplus-label or the Roxane-label products as brands, and, in some instances, varied the classification of the *same* product across time periods. (56.1 ¶¶ 221-24) For example, the Palmetto DMERC correctly placed the Novaplus product in its generic arrays from April to July 2003, even though it had misclassified the product as a brand in prior arrays. (*Id.*) After July 2003, Palmetto again re-classified the Novaplus product as a brand. Similarly, the Adminastar DMERC misclassified the Roxane-label ipratropium bromide as a brand for more than a year, from July 2002 to October 2003, even though Adminastar had classified it as a generic for the prior six years. (*Id.*) Adminastar then re-classified the product back to a generic after October

2003. (*Id.*) Both the Cigna and Adminastar DMERCs misclassified the Novaplus-label product as a brand throughout. (*Id.*)

The resulting jumble of contradictory classifications is partially explained by the adopted procedures, which, on their face, informed the DMERCs that these criteria could not differentiate brands from generics with any degree of certainty. (56.1 ¶¶ 221-24) Instead, the procedures merely stated they might identify Redbook entries that were "generally brands." (*Id.*) And, anticipating the potential confusion that would likely arise, the procedures required DMERCs to call manufacturers, such as Roxane, directly, or the Redbook itself, if classification questions arose. (*Id.*) Such classification questions plainly *should* have arisen, given that the DMERCs' decisions were often in direct conflict with each other, and, at times, in conflict with their own prior decisions from one quarter to the next. (*Id.*) There is no evidence, however, that any DMERC availed itself of this option and contacted Roxane or the Redbook for clarification. (56.1 ¶¶ 213-14)

Moreover, the DMERCs' errors become even more incomprehensible and attenuated from any cognizable theory of causation when one attempts to reverse engineer the DMERCs' cryptic methodology of interpreting Redbook listings.[17] Specifically, both the 2001 and 2002 Annual Redbooks (which are the first two years that the Novaplus AWPs appeared in the Redbook), list the Novaplus NDCs ***identically*** with respect to capitalization (and every other descriptor) to the Roxane-label ipratropium bromide, a product that *no one* in this litigation disputes was properly classified as a generic. (56.1 ¶¶ 184-210) In fact, the *only* distinction in

[17] The precise bases of the DMERCs' Novaplus classifications cannot be reconstructed because most of the evidence was destroyed during the intervening seven years that this case remained under seal. For instance, the electronic CDs that many DMERCs relied upon during this time automatically erased prior data with each quarterly update. (56.1 ¶¶ 211-12) These CDs were not preserved or produced by the Government.

the Redbook listings between the two products is the NDC numbers. (*Id.*) Thus, according to the DMERCs' own criteria, the Novaplus NDCs also should have been classified as generics not just by DMERC-A, but by the other three DMERCs as well. (*Cf.* 56.1 ¶ 180 *with* ¶¶ 221-24) In any event, the bases for the DMERCs' classifications here remain a mystery that eludes explanation even under their own procedures.

The DMERCs' unexplained exclusive reliance on Redbook compendia is yet another intervening factor that attenuates causation here. The governing regulation did not limit the DMERCs to Redbooks – they were free to consider other compendia sources, such as the First Data Bank (FDB) Blue Book, which is the principal source of AWPs for the Medicaid program. (56.1 ¶¶ 163, 215) In contrast to the Redbook, the FDB Blue Book has a host of indicators that specifically help identify generic drugs. (56.1 ¶¶ 215-20) Had the DMERCs looked at the FDB Blue Book, as contemplated under the governing regulation, they could have readily observed that ***all six*** generic indicators in the FDB Blue Book unambiguously flagged the Novaplus-label ipratropium as a generic drug. (*Id.*). Indeed, the FDB Blue Book generic indicators were *identical* for both the Novaplus and Roxane-label ipratropium bromide products. (*Id.*) Thus, it is perplexing why the DMERCs ignored such a widely used and recognized compendia, which had specific generic indicators (that cannot be found in the Redbook), and which clearly suggested the generic status of the Novaplus product. (*See generally* 56.1 at ¶¶ 215-20)

3. There Can Be No Causation Because There Is No Connection Between Reporting "False" AWPs And The DMERCs' Independent Decisions On How To Classify Generics And Brands.

Importantly, the DMERCs' misclassification of Novaplus as a brand had *nothing* to do with the alleged false statements here, which are the purportedly "inflated" AWPs Roxane reported. *See Fago v. M&T Mortgage Corp.*, 518 F. Supp. 2d at 122. The crucial inquiry for causation for damages under the FCA is whether the alleged damages "arose because of the

falsity of the claim." *Id.* (quoting *U.S. ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 200 (D.C. Cir. 1995)). Here, there is *no* connection between reporting an allegedly "false" AWP (*i.e.*, one that exceeds average acquisition cost) for the Novaplus product and the DMERCs' independent decisions to classify the drug as a brand or generic. This alone negates any causation. *See id.* at 122 (granting summary judgment on causation for damages under the FCA because plaintiff "failed to demonstrate any evidence showing that [the alleged bad conduct] was in any way related to the actual reason" for the alleged harm). Nor is there any evidence that Roxane had *anything* to do with the DMERCs' internal procedures for classifying drugs, or that in reporting allegedly "false" AWPs for the Novaplus ipratropium, Roxane instructed or advised the DMERCs that the product should be classified as a brand.[18] This too negates causation. *See United States ex rel. Kinney v. Hennepin County Med. Cntr.*, No. CIV. 971680, 2001 WL 964011 at **9-10 (D. Minn. Aug. 22 2001) (granting summary judgment because there was no evidence that defendant instructed or otherwise affected a separate party's intervening conduct).

Simply put, there is *no* evidence that could allow a jury to determine that it was foreseeable that the DMERCs would not only (1) ignore the regulatory definition and HCFA mandates, (2) substitute an entirely different classification methodology, but also (3) then fail to implement their own internal criteria consistently. To the contrary, the reasonably foreseeable expectation is that contractors, such as DMERCs, will follow HCFA's regulatory mandates. Indeed, this Court has previously determined that there can be no recovery for payment methodologies that deviated from regulatory requirements. *See Mylan*, 608 F. Supp. 2d at

[18] To the contrary, as discussed *infra* at Section V, *every* signal that Roxane sent to the marketplace indicated that the Novaplus-product was a generic.

147-48. Specifically, the State of Massachusetts was precluded from recovering for payments when it deviated from the regulatory requirement allowing use of only published WACs, and instead used published AWPs. *Id.* The Court's analysis depended on the unforeseeable nature of the State's deviation from regulatory mandates, which has equal application here. *Id.* In addition, the Government certainly has no evidence to show that DMERCs' deviations and errors were reasonably foreseeable to Roxane because the DMERCs' procedures and classification decisions were exclusively internal processes not visible to Roxane. (56.1 ¶ 162) *Cf. Franklin*, 2003 WL 22048255 at **4-5 (causation requires harm to be foreseeable). Thus, the misclassification of the Novaplus-product was entirely unknown to Roxane throughout the period. Accordingly, claims that depend on the DMERCs' regulatory deviations are foreclosed as a matter of law.

4. The Government's Newfound Theory That Novaplus Is A "Brand" Under the Regulation Is Pretextual.

Seeking to disregard the plain regulatory language, the Government has fabricated a *post-hoc* argument that the addition of the term "Novaplus" to the generic chemical name of "ipratropium bromide inhalation solution 0.02%" somehow converted the product into a brand under the regulatory definition. As an initial matter, this argument is a nullity because, as discussed above, the DMERCs unpredictably adopted their own idiosyncratic methodology. Setting aside that fundamental causation problem, the Government's argument here fails for the additional reason that it is contrary to the plain terms of the regulation: the presence of the word "Novaplus" merely identifies the supplier of the product, and does not otherwise alter the basic fact that the generic chemical compound "ipratropium bromide" is the front-and-center name of the product. (56.1 ¶¶ 142-46)

Moreover, the Government's newfound argument is pretextual. This argument arose only *after* the Government's late discovery that some of the DMERCs had committed these errors. Prior to that, the Government had acknowledged that Novaplus had "always" been a generic product. For instance, in September 2008, one of the senior Department of Justice attorneys leading this litigation acknowledged this fact in deposition questioning of the Adminastar DMERC's Rule 30(b)(6) representative:

> Q: Now I want to suggest to you, Ms. Eiler that ***Novaplus actually has always been a generic product, not a brand product***. And that if one – I want you to assume that if one had done additional research, the generic status of that drug might have been discovered . . ."
>
> * * *
>
> Q: Okay. I'd like you to assume today that ***in fact they're [Novaplus NDCs] generic drugs***, ***and that if you have done some additional research, besides just looking at the RedBook, you might have determined that they were in fact generics***.

(56.1 ¶ 180 (Eiler Dep. at 549, 558-59)) (emphasis added). Less than one month after the Government made these representations, it moved to amend its complaint to add the Novaplus NDCs. Several months later the Government issued expert reports that reversed course and now *embraced* the DMERCs' misclassification of Novaplus as a vehicle to artificially inflate the alleged damages. (56.1 ¶¶ 225-44) Thus, the Government's eleventh-hour addition of the Novaplus NDCs appears to be nothing more than gamesmanship and a blatant attempt to capitalize on the DMERCs' errors in the Government's made-up "but for" world.

C. Certain DMERCs' Failure To Update Their Pricing Arrays In A Timely Fashion Is An Additional Intervening Factor That Negates Causation.

To establish correct payments for generic drugs, the DMERCs were required to timely update their pricing arrays to include additional AWPs as they were added to the publishing compendia. (56.1 ¶¶ 156-73) In 2000, Zenith Goldline entered the ipratropium bromide market,

and, correspondingly, Red Book began publishing AWPs for Zenith's NDCs at least as early as April 2000. (56.1 ¶¶ 245-48) In July 2000, the Adminastar DMERC properly added these AWPs to its pricing arrays. (*Id.*) The other three DMERCs, however, inexplicably failed to update their arrays with these same AWPs. (56.1 ¶ 251)

The DMERCs' errors in timely updating their arrays have an enormous impact on Dr. Duggan's damages calculations. (56.1 ¶¶ 249-52) When Adminastar properly added the Zenith Goldline AWPs in July 2000, the AWPs for Roxane's drugs no longer affected the calculation of the median AWP, and Dr. Duggan's methodology properly dictates that there should be no damages for Roxane from that time onward. (*Id.*) But Dr. Duggan continues to assign $88 million of alleged damages in this time period based on the other DMERCs' failures to update their arrays with the very prices that Adminastar properly included. (*Id.*) There is no principled reason why these three DMERCs, purportedly operating under the *same* regulatory mandates, internal procedures, and publishing compendia as Adminastar, should ignore the Zenith Goldline AWPs. And there certainly is no basis in law to ascribe damages to Roxane based upon these failures to follow regulatory mandates. Accordingly, the Government cannot recover any damages beyond the July 2000 time period when Roxane AWPs should not have affected the median AWP.

V. THE GOVERNMENT CANNOT ESTABLISH SCIENTER BASED ON DMERCS' INTERVENING ERRORS.

In addition to being unable to establish causation, the Government also cannot establish scienter based on the DMERCs' errors. Under the FCA, the Government must prove that in "knowingly" reporting AWPs for the Novaplus-label product, Roxane actually knew or acted in deliberate ignorance or reckless disregard that certain DMERCs would place the Novaplus AWPs in brand versus generic pricing arrays. *See* 31 U.S.C. § 3729(a)(1), (2). The

Government, however, has *no* evidence that Roxane even knew – much less intended – that DMERCs would categorize this product as a brand. To the contrary, the undisputed evidence demonstrates that Roxane *always* believed these products were properly classified as generic drugs, and provided every possible indication to the marketplace of that fact. (56.1 ¶¶ 135-47) *First*, the Novaplus products entered the marketplace *years* after other generics had already penetrated the marketplace. (56.1 ¶¶ 135-42) Thus, there could be no question that these were not patent-protected products. *Second*, the Novaplus products were given the chemical compound name of "ipratropium bromide," just like every other generic ipratropium product in the marketplace. (56.1 ¶¶ 142-43) *Third*, the Novaplus products received *identical* AWPs as the Roxane-label ipratropium bromide, an undisputed generic drug, in contrast to the significantly higher AWPs for the brand product, Atrovent. (56.1 ¶¶ 137, 145) *Finally*, and significantly, the Novaplus products were sold at the same, or even lower, contract prices than Roxane's generic ipratropium bromide. (56.1 ¶ 146) Taken together, the undisputed facts defeat any attempt to establish that Roxane intended these products to be treated as brands.[19]

VI. ROXANE IS NOT LIABLE FOR ANY CLAIM POST-2000 BECAUSE THE "PERFECT STORM OF INFORMATION" NEGATES THE ELEMENTS OF SCIENTER AND FALSITY.

Plaintiffs cannot prove the required elements of scienter or falsity after 2000 and therefore summary judgment should be granted on all claims beginning in 2001.

[19] The Government similarly cannot establish scienter for the DMERCs' failure to timely update their arrays, as discussed *supra* in Section IV(C).

A. Roxane Cannot Have The Requisite Scienter, Given the Widespread Information On Drug Pricing And Submission Of AMPs To The Government.

The Government cannot satisfy its burden to establish that Roxane had "knowledge" of the alleged falsity of its statements and/or claims. *See* 31 U.S.C. § 3729(a)(1), (2); *Mylan*, 608 F. Supp. 2d at 140. The information available to the Government at the latest by 2001, which showed so-called "mega-spreads" between AWP and acquisition costs for generic drugs and in particular for Roxane's drugs such as ipratropium bromide, was "'*so extensive* that [Roxane] could not as a matter of law possess the requisite state of mind to be liable under the FCA.'" *Mylan*, 608 F. Supp. 2d at 149 (quoting *Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 534 (10th Cir. 2000) (emphasis in original)).[20] (56.1 ¶¶ 1-95) In other words, "'the government's '*full knowledge of the material facts* underlying [reported AWPs that greatly exceeded actual acquisition costs] . . . negates any knowledge that [Roxane] had regarding the truth or falsity of those representations.'" *Mylan*, 608 F. Supp. 2d at 149 (quoting *U.S. ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) (emphasis in original)); s*ee also U.S. ex rel. Englund v. Los Angeles County*, No. CIV. S-04-282 LKK/JFM, 2006 WL 3097941, **12-13 (E.D. Cal. Oct. 31, 2006) (granting defendants' motion for summary judgment because extensive government knowledge of defendants' "scheme" negated the intent requirement).

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[20] *See also Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) (granting summary judgment to defendant where alleged false claim was submitted based on agency knowledge); *U.S. ex rel. Butler v. Hughes Helicopters, Inc.*, 71 F.3d 321, 328 (9th Cir. 1995); *U.S. ex rel. Gudur v. Deloitte Consulting LLP*, 512 F. Supp. 2d 920, 932 (S.D. Tex. 2007).

B. Given This Widespread Information Of Generic Drug Pricing, The Government Cannot Establish The Element of Falsity.

The FCA requires proof of falsity, which cannot be met here. 31 U.S.C. § 3729(a)(1), (2); *Mylan*, 608 F. Supp. 2d at 140. As this Court has acknowledged, when a government is fully informed of large-scale spreads, but continues to rely upon a payment system incorporating those spreads as a policy matter, government knowledge is a viable defense. *Mylan*, 608 F. Supp. 2d at 152 ("With respect to the post-2002 period, a government knowledge defense is viable because the government decided to continue using WACs as a policy matter.") In this case, the record is replete with testimony from HCFA Administrators – the senior individuals with leadership responsibility for running the Medicare and Medicaid programs – who candidly acknowledge the political and policy choices that led to the continuation of reimbursement based on AWP, even in the face of widespread awareness that the Government was paying amounts significantly greater than actual acquisition costs. *See infra* Section VI.G. (56.1 ¶¶ 1-63, 66-73) The Government's decision to continue to reimburse Roxane's drugs based on AWP as a policy matter negates any claim of falsity as a matter of law.[21] (56.1 ¶¶ 66-79)

C. By 2001 All Pertinent Players In The Marketplace Knew Of Extensive And Large Spreads, Particularly Among Generic Drugs.

As this Court held in the MDL class action, "[b]y 2001, there was a perfect storm of information that reflected the size of the spreads, largely because of the compelling information collected by the HHS Office of Inspector General ('OIG')." *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 41 (D. Mass. 2007). (56.1 ¶¶ 1-95) Tellingly, this Court determined that, by 2001, information pertaining to "mega-spreads" was so pervasive that

[21] *See also U.S. ex rel. J. Cooper & Assocs. v. Bernard Hodes Group*, 422 F. Supp. 2d 225, 239 (D.D.C. 2006).

such large-scale discrepancies were no longer deceptive as a matter of law – even to "less-sophisticated participants, like Taft-Hartley Plans."[22] *Id.* at 40, 41, 95. Indeed, this Court has repeatedly noted that by 2001 – at the latest – the "Government knew" of mega-spreads.[23]

The record evidence in this case reveals that the "perfect storm of information" was exponentially more extensive for the plaintiff here, the United States.[24] Unlike the third-party payors and consumers in the MDL, the United States (1) administers and runs the Medicare program, (2) supervises the federal-State Medicaid program by reviewing and approving all proposed payment methodologies for drugs, and, as discussed below, (3) *directly* received quarterly Average Manufacturer Prices (AMPs) from Roxane for *every* NDC since 1991. (56.1 ¶¶ 128-34) At a minimum by 2001, the Government cannot reasonably dispute that the mega-spreads between published AWPs and the actual acquisition costs of generic drugs were no longer "secret." *Id.* at 31. (56.1 ¶¶ 1-63, 66-73)

D. The Record Confirms That The Government Had An Abundance Of Information Regarding The Pricing Of Generic Drugs.

In every quarter since 1991, according to statutory mandates, Roxane has provided HCFA with the AMPs of all of its generic drugs. (56.1 ¶¶ 156-26) AMPs are defined as "the

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22 The statute at issue in the MDL trial was the Massachusetts Unfair and Deceptive Trade Practices Act, which has both a 'deceptive' acts prong and an 'unfair' acts prong. Although the Court determined that as of 2001, published AWPs that resulted in 'mega-spreads' were no longer deceptive, it held that the continued publication of such AWPs was unfair because of the length of time it took the Government to make changes. Here, under the False Claims Act, there is no liability akin to 'unfair' acts; rather, the controlling issues of falsity and knowledge of falsity are similar to the 'deceptive' issue in the MDL.

23 "The government knew. The government knew. The government knew. At least from all those OIG reports, they knew." *In re Pharm. Indus. Avg. Wholesale Price Litig.*, Civ. Action No.: CA No. 01-12257-PBS, Mot. Hr'g, 11/5/07, pp. 46.

24 The extensiveness of information is also amplified significantly for the type of drug at issue in this case: generic self-administered drugs ("SADs"). In the MDL, this Court recognized that there was significantly more pricing information for SADs than for the physician-administered drugs ("PADs") that were the focus of the MDL. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 39-40 (D. Mass. 2007).

average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade," "inclusive of cash discounts, free goods, . . . volume discounts, and rebates." 42 U.S.C. § 1396r-8(k)(1); H.R. No. 101-881 (reprinted in 1990 U.S.C.C.A.N. 2017, 2060 (1990)). Thus, by 2001, the Government had been receiving AMPs for Roxane's drugs for 10 years. (56.1 ¶¶ 156-26) Because AMPs represent fully-discounted average prices for drugs distributed to pharmacies, the Government has long possessed particularized information regarding the degree to which Roxane's AWPs exceeded actual costs of its drugs to pharmacy providers. Contrary to the Government's litigation-driven arguments, nothing in the statute requiring manufacturers to report AMPs prevented the Government from reviewing or relying on AMPs. *See* 42 U.S.C. § 1396r-8(b)(3)(D) (stating only that AMP shall not be disclosed "in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs"); (56.1 ¶ 133) To the contrary, Roxane sent AMPs to the Government for the very purpose of having the Government use those AMPs. (56.1 ¶¶ 125-31) In fact, federal agencies such as the Congressional Budget Office ("CBO") did compare AMPs to AWPs and openly reported the differences between those figures to the public. (56.1 ¶ 129) In addition, the OIG, which this Court characterized as the "government's pit bull," had unfettered access to AMP data for the purposes of its drug pricing investigations. (56.1 ¶ 128)

Moreover, key senior Government officials confirmed that HCFA, the White House, and Congress had intricate and extensive information that reflected the size of discounts available for purchasers of generic drugs. For instance:

- Bruce Vladeck, HCFA Administrator from 1993 to 1997, admitted that HCFA not only "knew all along we were overpaying for drugs in the Medicare program," but also was aware of mega-spreads exceeding "500 percent, and in some instances more than 1,000 percent." (56.1 ¶ 26)

- Former HCFA Administrator Thomas A. Scully believed, since 1990-91, when he was the senior White House staff member on health care, that AWP itself was "air" – a "completely contrived number." (56.1 ¶ 18)

- Congress also had extensive information about the nature of AWPs. House Representative Pete Stark, the ranking member of the Ways and Means Subcommittee on Health, the Congressional committee that oversaw the budgets for Medicare and Medicaid, informed Congress in 1996 that AWP "is grossly overstating the true price of these drugs." (56.1 ¶ 28)

Furthermore, OIG inundated HCFA with numerous pricing reports before 2001 that detailed large-scale spreads across a wide category of generic drugs:

- In September 1989 – seven years before the pertinent period in this Complaint – the OIG specifically cautioned HCFA that "AWP is not a meaningful figure, and that it should not be used for making reimbursements in either the Medicaid or the new Medicare drug program." (56.1 ¶ 11) Nonetheless, HCFA not only adopted published AWP as a payment methodology for Medicare Part B drugs in 1991, it also decided to pay based on ***an undiscounted AWP***. (56.1 ¶ 16)

- In August 1997, the OIG published a national summary report concluding that the average actual acquisition cost of generic drugs was 42.5% below AWP—a mega-spread of 74%. (56.1 ¶¶ 21, 48)

- In December 1997, the OIG further cautioned HCFA that "[t]he published AWPs . . . bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs." (56.1 ¶ 35)

On March 19-20, 1998, Ven-A-Care met with representatives from the majority of State Medicaid programs, the National Association of Medicaid Fraud Control Units ("NAMFCU"), and Nancy-Ann Min DeParle of HCFA, and presented detailed information about "grossly excessive payments," involving spreads frequently in the hundreds of percents, and up to 3,000%. (56.1 ¶ 42) Ven-A-Care also described "how the spread was used as a marketing tool [by manufacturers]." (56.1 ¶ 42) Moreover, in 1999, HCFA commissioned a drug pricing study and report by Myers & Stauffer, an accounting firm with substantial experience in performing studies of pharmacy acquisition cost and dispensing fees for numerous State Medicaid programs and HCFA. (*See* 56.1 ¶ 47) In its report for HCFA, Myers & Stauffer concluded that discounts

off of AWP for generic drugs averaged 58% and climbed as high as 90%, the equivalent of 138% and 900% spreads, respectively. (56.1 ¶ 47)

HCFA also had FUL prices for several of the drugs at issue in this case, which revealed the extent to which AWP did not reflect the average acquisition cost of providers. (56.1 ¶¶ 116-18, 120) In establishing FUL prices, HCFA engaged in a "manual review" whereby it often adjusted FULs generated by the automated system to ensure the price (a) would "achieve a cost savings," (b) would be at a level that ensured providers could acquire the drug in the marketplace, and, (c) would not cause access-to-care issues. (56.1 ¶ 118) In fact, HCFA acknowledged that it was "building into [FUL] rates for ingredients a profit margin for pharmacists." (*Id.*) Because the AWPs of the drugs at issue here were higher than the FUL – and in many instances significantly so – the FUL revealed the degree to which the AWP was not representative of provider cost. (*Compare* 56.1 ¶ 120 *with* Am. Compl. Exs. A, B.)

Thus, the record in this case further bolsters the findings of this Court in the MDL trial and makes clear that, by 2001 at the *latest*, the federal Government had extensive knowledge of the extent to which AWPs exceeded actual acquisition costs, particularly with respect to generic drugs. (56.1 ¶¶ 1-63, 66-73)

E. The Government Also Had Specific Pricing Information About The Magnitude Of Discounts Available For Purchasers Of Ipratropium Bromide.

The Government also had specific pricing information for ipratropium bromide, one of the drugs at issue in this case:

- In November 1998, the OIG reported that the Department of Veterans Affairs was able to purchase ipratropium bromide at less than half the price that HCFA was paying for Medicare reimbursement – equivalent to a "spread" of 155%. (56.1 ¶ 83)
- In 1999, Representative Stark demonstrated Congress's intricate knowledge of increasingly large spreads for ipratropium bromide. He issued a press release showing ipratropium bromide spreads of 63% in 1997, 96% in 1998, and 106% in 1999. (56.1 ¶ 85)

- Former HCFA Administrator Thomas Scully admitted that he, too, was aware of "mind blowingly big margins" for ipratropium bromide. (56.1 ¶ 88) In addition, a Government Accountability Office ("GAO") report specifically commissioned by Congress, concluded that "two drugs used with durable medical equipment had discounts of 78% and 85%, equating to 'spreads' of 355% and 567%." *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 43 (citing GAO, Report to Congressional Committees, Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost ("GAO Report"), at 4). (56.1 ¶ 87) One of those drugs was *ipratropium bromide*. (56.1 ¶ 87)

F. By 2001, The Government Had Pinpoint Data Detailing The Purported "Mega Spreads" Of The Roxane Drugs At Issue Here.

Shortly after Ven-A-Care filed its first complaint against Roxane in 2000, it provided the Government with a complete working database that included pinpoint pricing data from the McKesson wholesaler for ***all*** Roxane drugs. (56.1 ¶¶ 91-95) This database included an automatic pop-up window that instantly calculated the "spread." (56.1 ¶ 94) It took less than five minutes to generate a report showing the exact "mega spreads" for all Roxane drugs. For instance, the October 23 and December 12, 2000 printouts from this database, which were provided to the Government in January 2001, showed purported "mega-spreads" of 386% for ipratropium bromide, 1,483% for furosemide, and 200% for azathioprine. (56.1 ¶¶ 93, 95) Thus, there can be no doubt that by 2001 – at the very latest – the Government was fully informed of the precise differences between AWPs and acquisitions costs on each and every Roxane product, and the alleged "secret" spreads were plainly revealed. (56.1 ¶¶ 1-63, 66-73, 80-95)

G. The Government Repeatedly Rejected Attempts To Reimburse At Levels Closer To Actual Acquisition Cost.

The Government's history is replete with resistance to attempts to require drug payments to be closer to an average acquisition cost. (56.1 ¶¶ 12-16, 50-57, 66-73) As discussed above, the Government had sufficient information at its disposal that would have enabled it to lower reimbursement payments to align more closely with the acquisition cost of drugs. (56.1 ¶¶ 1-11,

17-49, 58-65) Yet, the Government deliberately – and repeatedly – chose not to do so, for policy reasons. For example:

- ***Congress rejects President Clinton's proposal in 1997-1998 to move to a reimbursement formula based on actual acquisition cost, despite knowledge of spreads of up to 900%.*** (56.1 ¶ 52)
- ***Congress rejects even minimal discount of AWP-17% both in 1999 and 2000.*** (56.1 ¶ 55)
- ***Congress rejects the use of DOJ AWPs, which were akin to actual average acquisition cost, in 2000 –*** because, *inter alia*, it would "impact quality and access to care issues." Significantly, more than 90 Congressional members specifically told HCFA that Medicare *must* use the AWP in publishing compendia, a figure widely known as an unreliable proxy for acquisition cost, rather than the DOJ AWPs. (56.1 ¶¶ 61-62, 66-73)

Numerous HCFA Administrators confirmed that the Government chose, as a policy matter, to continue reimbursing based on AWPs/WACs that provided margins to providers. For instance, Bruce Vladeck admitted that in the mid- to late-1990s, he and HCFA believed that the Government was significantly overpaying for Medicare Part B drugs, but that the Government did not change the reimbursement methodology largely because of "political considerations." (56.1 ¶ 56) In particular, he noted that urologists, other oncologists, and the American Society of Clinical Oncology were very aggressive, and strongly opposed proposals to pay less than 100% of AWP and to move away from AWP as a reimbursement basis. (*Id.*) In fact, the former head of HCFA asserted that the Government chose ***not*** to move to a reimbursement methodology based on actual acquisition cost because of political reasons. (*Id.*) Moreover, ***even today***, the Government continues to utilize AWP as a basis for Medicaid and Medicare Part D reimbursement payments. (56.1 ¶¶ 74-79) For example, CMS – the agency with oversight responsibility for the Medicare and Medicaid programs – recently stated that it "fully

encouraged" generic drug acquisition costs of AWP-73% – a spread of 270%[25] – because it "provides good value to both the beneficiary and the taxpayer . . . ." (56.1 ¶ 79)

In short, the robust factual record indisputably shows that by 2001 – at the latest – the Government had detailed knowledge of the extent of inflated AWPs, yet the Government eschewed regulatory or statutory change for policy reasons. (56.1 ¶¶ 1-63, 66-73)

VII. THE GOVERNMENT'S PRE-2001 CLAIMS ARE TIME-BARRED UNDER THE FCA'S SIX-YEAR STATUTE OF LIMITATIONS.

Under Title 31 U.S.C. § 3731(b), claims asserted under the FCA are time-barred unless they are brought within six years of the date of the alleged violation. The Government filed its Complaint-in-Intervention on January 18, 2007 and its Amended Complaint (the "Complaint") on December 2, 2008, alleging that its claims "relate back to the dates of the original pleadings in this case." (Dkt. No. 96 ¶ 17.) The Government's claims cannot relate back, however, to *any* of the complaints that Ven-A-Care filed in this action because this Court never acquired jurisdiction over any of Ven-A-Care's complaints. As discussed in Roxane's Memorandum in Support of Motion to Dismiss for Lack of Subject-Matter Jurisdiction Under the Public Disclosure Bar of the False Claims Act ("Motion to Dismiss"), filed contemporaneously with the instant Motion, this Court lacks jurisdiction over Ven-A-Care's claims. Indeed, as shown in the Motion to Dismiss, this Court never acquired jurisdiction over Ven-A-Care's claims because, at all times since the inception of this action, Ven-A-Care has failed to satisfy the jurisdictional prerequisites under Title 31 U.S.C. § 3730(e)(4). As a result, those pleadings are a nullity and

[25] Under the Government's methodology, spreads are calculated as the percentage above acquisition cost of the AWP, as opposed to discounts off of AWP.

cannot serve as a legitimate placeholder for relation back purposes. Accordingly, the Government's claims are all time barred to the extent they accrued prior to January 18, 2001.

A. The Complaint Cannot Relate Back To Any Of Ven-A-Care's Pre-Intervention Complaints Because They Were Jurisdictionally Defective.

A complaint filed in a court that lacks jurisdiction in the first place is not an adequate basis for relation back because it is impossible to relate back to something that *de jure* never existed. *See Holloway v. United States*, 60 Fed. Cl. 254, 261, 264 (2004); *In re Eldridge*, 348 B.R. 834, 846 (N.D. Ala. 2006). Indeed, this Court has already acknowledged as much by holding that the Government's complaint could not relate back to Ven-A-Care's original pleading, if the Court lacked jurisdiction over that pleading. *In re Pharms. Indus. AWP Litig.*, 498 F. Supp. 2d 389, 399-400 (D. Mass 2007). These concepts are founded on the well-established principle that relation back is unavailable if it would retroactively create jurisdiction where none existed in the first place. *See USM Corp. v. GKN Fasteners Ltd.*, 578 F.2d 21, 23 (1st Cir. 1978).[26] Because Ven-A-Care did not, and cannot, satisfy the jurisdictional requirements under § 3730(e)(4), each of Ven-A-Care's complaints was fatally defective. Thus, permitting the Government to invoke relation back would retroactively extend the jurisdiction of this Court to claims that § 3730(e)(4) prohibited it from entertaining in the first place.

Nor does the fact that the Government has intervened somehow revive or cure the defects in Ven-A-Care's claims, such that they could furnish a viable basis for relation back. *See U.S. ex rel. Cosens v. Yale-New Haven Hosp.*, 233 F. Supp. 2d 319, 326 (D. Conn. 2002);

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[26] *See also Cicchetti v. Lucey*, 514 F.2d 362, 367-68 (1st Cir. 1975); *Pressroom Unions-Printers League Income Sec. Fund. v. Cont'l Assur.*, Co., 700 F.2d 889, 893, n.9 (2nd Cir. 1983); *Miguel v. Country Funding Corp.*, 309 F.3d 1161, 1165 (9th Cir. 2002); *New Bank of New England, N.A. v. Tritek Commc'ns, Inc.*, 143 F.R.D. 13, 16-20 (D. Mass. 1992); *Reynolds v. United States*, 748 F.2d 291, 293 (5th Cir. 1984); *Fuller v. Volk*, 351 F.2d 323, 328-29 (3rd Cir. 1965); *Aetna Cas. & Sur. Co. v. Hillman*, 796 F.2d 770, 774-75 (5th Cir. 1986).

U.S. ex rel. Krahel v. Regents of Univ. of Cal., Nos. C-96-1703, C-01-1893, 2001 WL 1548786, **3-4 (N.D. Cal. Sept. 13, 2001). Indeed, courts have reached just the opposite conclusion – that the intervention of a plaintiff that *can* satisfy the jurisdictional requirements of the FCA does not cure the defective claims of a relator who *cannot*. *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 476-77 (2007); *Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447, 452-53 (D. Conn. 1995). Although courts may exercise jurisdiction over an intervening plaintiff's claims, such claims have the characteristics of a separate action, and thus cannot relate back to the original pleading. *See Fuller v. Volk*, 351 F.2d 323, 328-29 (3d Cir. 1965).[27]

The cases cited by the Supreme Court in *Rockwell* further support this conclusion. In *Rockwell*, the Court held that, while it did not have subject matter jurisdiction under § 3730(e)(4) over the *relator's* claims, it could nonetheless retain jurisdiction over the *Government's* claims, by dismissing the relator from the action. *Rockwell*, 549 U.S. at 478. In support of this conclusion, the Court cited *United States Steel Corp. v. EPA*, in which the original plaintiff was also dismissed from the action after the intervention of another plaintiff. *Id*. As in *Rockwell*, the court in *U.S. Steel* held that the intervening plaintiff could continue to litigate its claims after the original plaintiff was dismissed. *U.S. Steel*, 614 F.2d 843, 845-46 (3rd Cir. 1979). The court observed, however, that although it "has discretion to treat the pleading of an intervenor as a *separate action* in order that it might adjudicate the claims raised by the intervenor," "intervention cannot cure a jurisdictional defect." *Id*. at 845.

In addition, the First Circuit has also rejected the notion that relation back can be used to manufacture a jurisdictional element, the absence of which precluded judicial review in the first

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[27] *See also Summit Office Park, Inc. v. United States*, 639 F.2d 1278, 1284-85 (5th Cir. 1981); *U.S. Steel Corp. v. EPA*, 614 F.2d 843, 845 (3d Cir. 1979); *Pressroom*, 700 F.2d at 893, n.9; *Fuller*, 351 F.2d at 328-29.

place. *USM Corp.*, 578 F.2d at 22. The First Circuit's observations in *USM Corp.*, are particularly instructive here:

> The effect of the amended pleadings on this court is to alter our jurisdictional scope: by retroactively changing the nature of the action it filed . . . , the appellant attempts now to create ex post facto a jurisdictional element whose absence earlier precluded our review. We do not wish to suggest that the motion to amend should not have been granted. We merely limit the effect of the amended pleadings on the jurisdiction of this court.

Id. at 22, n.2.

Accordingly, the claims asserted by the Government are properly considered a new action, which, at best, can only relate back to the Government's 2007 Complaint. To hold otherwise would permit the Government to create *ex post facto* the jurisdictional elements that Ven-A-Care in its prior complaints could not satisfy. As a result, all claims that accrued before January 18, 2001 are time-barred.

VIII. THERE IS NO EVIDENCE TO SUPPORT THE GOVERNMENT'S UNJUST ENRICHMENT CLAIMS.

The Government contends that Roxane was unjustly enriched at its expense as a result of alleged "inducements . . . paid to Roxane's customers." (Am. Compl. ¶ 76, Count III). Unjust enrichment requires proof of: "(1) an enrichment, (2) an impoverishment, (3) a relation between the enrichment and the impoverishment, (4) the absence of justification, and (5) the absence of a remedy provided by law." *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 182 (D. Mass. 2003) (quotations omitted). Thus, the Government must show that "wealth is 'in one person[]'s hands when it should be in another's.'" *Massachusetts v. Mylan Labs. Inc.*, 357 F. Supp. 2d 314, 324 (D. Mass. 2005) (citing *Guyana Tel. & Tel. Co. v. Melbourne Int'l*

Commc'ns, 329 F.3d 1241, 1245, n.3 (11th Cir. 2003)). Here, there is no evidence to support the theory that Roxane was enriched under the circumstances of this case.[28]

As an initial matter, Roxane is not a provider and does *not* receive Medicaid or Medicare reimbursement payments. Thus, there can be no unjust enrichment based on receipt of Government funds here. To the extent the Government's theory depends on showing that Roxane received an alleged indirect benefit in the form of increased market share or profits, the Government has ***no*** evidence to support this theory, much less any analyses by its expert. (*Cf.* Am. Compl. ¶ 63) In response to a Roxane interrogatory asking for evidence supporting the unjust enrichment claim, the Government merely stated:

> Through reporting inflated prices, Roxane ensured that its customers received inflated reimbursement from Medicare and Medicaid. Roxane then knowingly promoted "spreads" between its fraudulently inflated prices and its actual sales prices as an inducement to its customers.

(56.1 ¶ 255) Yet, the record is completely devoid of evidence showing how or if Roxane actually benefited – or was enriched – from marketing any alleged "spreads." The Government has not proffered any evidence of competitive spreads, induced customers, market shares, or changes in market shares, let alone evidence of a causal connection between comparative AWPs and WACs and levels or changes in market shares. Indeed, the evidence is directly contrary. For example, Roxane's ipratropium bromide sales decreased dramatically ***precisely*** during the time

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[28] The unjust enrichment claim is also barred because the United States has an adequate remedy at law through its FCA claim, which seeks redress beyond or coextensive with redress available under the principles of equity. *See, e.g.*, *United States v. Buckley*, No. 0011632, 2005 WL 164287, at *1 (D. Mass. Jan. 25, 2005) (granting summary judgment to defendant and dismissing unjust enrichment claim where plaintiff had an adequate remedy at law through its FCA claim). Additionally, the statute of limitations bars any unjust enrichment relief prior to January 23, 2001 – six years prior to the unsealing of the United States' complaint against defendants. *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 498 F. Supp. 2d 389, 400-01 (D. Mass. 2007) ("28 U.S.C. § 2415(a), which provides a six-year limitations period, controls the government's claim of unjust enrichment.").

period when the purported "spreads" were growing dramatically. (56.1 ¶ 256) Because the record is simply devoid of any evidence supporting the Government's unjust enrichment theory, summary judgment on Count III is warranted.

IX. THE GOVERNMENT HAS NO EVIDENCE TO SUPPORT DAMAGES FOR MEDICARE CLAIMS PERTAINING TO AZATHIOPRINE.

The Government also has no evidence to support damages for any Medicare claims for azathioprine.[29] The Government's damages expert failed to conduct any analyses with respect to this drug:

> Q: . . . There is another drug, azathioprine. Did you do any analysis or form any opinions with respect to that drug?
>
> A: For Medicare, no. And to the extent that it's – I may have done some within Medicaid. But for Medicare, no.

(56.1 ¶ 257) Plaintiff has not set forth any evidence that it was harmed or otherwise damaged with regard to Medicare claims for azathioprine, and therefore Roxane should be granted summary judgment on any Medicare-related damages for azathioprine claims. *See U.S. ex rel. Ervin & Assocs., Inc. v. Hamilton Sec. Group, Inc.*, 370 F. Supp. 2d 18, 55 (D.D.C. 2005) ("Under the False Claims Act, damages must be proven with reasonable certainty."); *U.S. v. Collyer Insulated Wire Co.*, 94 F. Supp. 493, 499 (D.R.I. 1950) (damages in FCA cases cannot be the subject of "speculation or guesswork").

CONCLUSION

For all the foregoing reasons, the Court should grant the Roxane Defendants' Motion for Summary Judgment.

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[29] Although it is true that the Government need not prove damages in a FCA case, *Rex Trailer Co. v. United States*, 350 U.S. 148, 153, n.5 (1956); *U.S. ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991), when actual damages are sought, the statute requires a preponderance of evidence standard be satisfied. 31 U.S.C. § 3731.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on June 26, 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ John W. Reale
John W. Reale